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09/819,157	03/27/2001	Jonathan L. Coffman	GFN-002	2662

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,157

Applicant(s)

COFFMAN ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. Claims 1, 19, and therefore dependent claims 2, 3, and 20-25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-16, 18-20, 23, 26-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 4-16, 18-20, 23, 26-33 are directed in to a method for purifying PSGL-1 via a two step purification procedure wherein the second step (via metal chelate chromatography or hydrophobic interaction chromatography) the salt concentration of the elution solution is lower than in the washing solution. The breadth of the claim is directed to a method of purifying a highly anionic target molecule that may be optionally comprise a Fc domain. When broadly

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defined, a highly anionic target molecule would read upon any molecule with a negative charge (fatty acids, proteins, small molecules, etc.), thus, the claims recite a method of purifying any anionic compound via a two step purification procedure wherein the second step (via metal chelate chromatography or hydrophobic interaction chromatography) the salt concentration of the elution solution is lower than in the washing solution. The specification teaches the processes and conditions necessary for the purification of PSGL-1. The specification proves no guidance as to the purification of any other protein or highly anionic target molecule. The structure and identity of another protein or molecule other than PSGL-1 is not presented. As such, the specification has provided only the set of conditions necessary to purify PSGL-1.

Therefore, to a method for purifying PSGL-1 via a two step purification procedure wherein the second step (via metal chelate chromatography or hydrophobic interaction chromatography) the salt concentration of the elution solution is lower than in the washing solution, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "highly" in claim 1 (see lines 1, 5, 7 and 9) is a relative term which renders the claim indefinite. The term "highly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also claims 4, 19 (lines 1, 4 and 8), 24, and 26 (lines 1, 4 and 10).

Claim 2 recites the limitation "sulfated proteins" for which there is insufficient antecedent basis for this limitation in the parent claim 1. (see also claim 3.)

Claim 21 recites the limitation "sulfated molecules" for which there is insufficient antecedent basis for this limitation in the parent claim 19.

Claims 2-3, 5-18, 20-25, and 27-35 as they depend from indefinite claims 4, 19, 21, 24, and/or 26 and do not clarify the ambiguity.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings *et al.* (US 5,852,175; IDS B1). Cummings *et al.* teach the use of P-selectin in an affinity chromatography column for the purification of a P-selectin ligand, which is P-selectin Glycoprotein Ligand-1 or PSGL-1 (see column 7, lines 1-21). Cummings *et al.* puts into contact a sample into contact with both an albumin-Affigel and P selectin-Affigel to purify PSGL-1

ligand (both albumin and P-selectin would have bound the anionic or sulfated PSGL-1; regarding claims 1-3, 4a, 15 and 17). The above columns were first washed with buffer to remove the plurality of proteinaceous and non-proteinaceous impurities (regarding claims 1-3, 4b, 15 and 17) and then psgl-1 was eluted from the column and collected (regarding claims 1-3, 4(c,d), 15 and 17). The elution process and dialysis taught by Cummings *et al.* would have removed from the sample a plurality of proteinaceous and non-proteinaceous impurities. The pH of the wash buffer was 7.5 (regarding claims 5, 6 and 16). Thus, the reference anticipates the claimed invention.

6. Claims 1-7 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Larsen *et al.* (US 5,827,817; IDS A3). Larsen *et al.* teach the P-Selectin Glycoprotein Ligand-1 (PSGL-1) and PSGL-1 fusion protein to immunoglobulin or fc domain. In Example 14, Larsen *et al.* teach the use of an ion exchange column for the purification of PSGL-1 (regarding claims 1-4). The pH of the wash solution is 7.4 (regarding claims 5 and 6). The PSGL-1 was then furthered purified on an agarose column (regarding claim 7). PSGL-1 was cloned in Example 5 (regarding claim 18). Thus, the reference anticipates the claimed invention.

7. Claims 1, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Naveh *et al.* (US 5,034,133). Naveh *et al.* teach the purification of an anionic protein on a cationic exchange resin involving the washing, eluting and collecting of the sample (see Examples 1, 7 and 8; regarding claims 1, 4, 7). The wash buffer had a pH of 7.2 (see Example 6(a); regarding claims 5-6). The sample was then applied to a metal chelate column and elute by a declining salt

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gradient (see examples 2, 3, 4, 8 and 9; regarding claims 8-9). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 19-22, 26, 28, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsen *et al.* (US 5,827,817; IDS A3) in view of Scopes (Protein purification : principles and practice 2nd ed. New York : Springer-Verlag, c1987, pages 176-179). Larsen *et al.* teach the P-Selection Glycoprotein Ligand-1 (PSGL-1) and PSGL-1 fusion protein to immunoglobulin or Fc domain. In Example 14, Larsen *et al.* teach the use of an ion exchange column for the purification of PSGL-1 (regarding claims 1-4). The pH of the wash solution is 7.4 (regarding claims 5 and 6). The PSGL-1 was then further purified on an agarose column (regarding claim 7). PSGL-1 was cloned in Example 5 (regarding claim 18). Additionally, Larsen *et al.* teach a multiple step purification process for PSGL-1 (column 14, lines 36-60). Larsen *et al.* suggest several purification strategies and combinations and specifically suggest the use of a hydrophobic interaction column (see column 15, line 12; regarding claim 8). Larsen *et al.* teach PSGL-1 fusion protein to an Fc domain, suggesting their purification as above (see for example, column 9, line 35-47; regarding claims 19-22 and 26, 28, 32-35).

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Scopes teach that the protein is eluted off of a hydrophobic interaction column by lowering the salt concentration. Hence, the wash solution would have a greater salt concentration than the eluting solution (see page 177; regarding claim 9).

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to purifying PSGL-1 via a two step purification procedure wherein in the second step the salt concentration of the elution solution is lower than in the washing solution. A person of ordinary skill in the art would have been motivated to perform the purification of PSGL-1 as above because the steps of the method are suggested by Larsen *et al.* and the wash and elution relative salt concentrations are discussed in the general teachings of Scopes. A person of ordinary skill in the art would have expected success in using these standard and well established purification techniques. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

June 16, 2003

SKS

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